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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

GEORGE E. NAKASHIMA, M.D. and BELLAFLOR A. TROMPETA, M.D., a Medical Corporation, on behalf of themselves and all others Similar situated, Plaintiffs, v. MERCK & CO., INC., Defendant.	Case No. 14 6447 CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE SHERMAN ACT AND THE CALIFORNIA UNFAIR COMPETITION LAW

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PRELIMINARY STATEMENT

Plaintiffs, George E. Nakashima, M.D. ("Dr. Nakashima") and Bellaflor A. Trompeta, M.D., a Medical Corporation ("Dr. Trompeta") (collectively "Plaintiffs"), on behalf of themselves and all others similarly situated, bring this class action against Defendant, Merck & Co., Inc. ("Merck"). For their Class Action Complaint ("Complaint"), Plaintiffs allege as follows, based upon information and belief, Plaintiffs' counsel's investigation, and a *Qui Tam* action filed by Stephen A. Krahling and Joan A. Wlochowski (the "Relators") captioned *Krahling v. Merck & Co., Inc.*, Case No. 2:10-cv-04374-CDJ (E.D. Pa.) (the "*Qui Tam* Action").

INTRODUCTION

1. In 2006, and then again in 2009, the largest mumps outbreaks in two decades occurred in the United States in a highly vaccinated population. According to leading experts and an article published in *The New England Journal of Medicine*, these "unexpected" outbreaks were characterized by "two-dose vaccine failure." Thus, it was declared that "[a] more effective mumps vaccine or changes in vaccine policy may be needed to avert future outbreaks and achieve the elimination of mumps."

2. Although these outbreaks of mumps took physicians and the scientific community by surprise, Merck, the exclusive supplier of the mumps vaccine (including M-M-R®II and ProQuad®) (collectively, "Mumps Vaccine") in the United States, knew for at least a decade that its vaccine was far less effective than it claimed.

3. This lawsuit is brought as a class action by Plaintiffs against Merck for, among other violations, unlawfully monopolizing the United States market for Mumps Vaccine by engaging in a decade-long scheme to falsify, misrepresent, and conceal the true efficacy of its vaccine.

4. Specifically, Merck fraudulently represented and continues to falsely represent in its labeling and elsewhere that its Mumps Vaccine has a "high degree" of efficacy, with at least a 95 percent efficacy rate.

5. Merck manufactures its Mumps Vaccine using an attenuated virus. An attenuated virus is created when its pathogenicity has been reduced so that it will initiate an immune response without producing the specific disease. Pathogenicity is reduced by "passaging" the virus through a series of cell cultures or animal embryos. With each passage, the virus becomes better at replicating in the host, but loses its ability to replicate in human cells. Eventually, the attenuated virus will be unable to replicate well (or at all) in human cells, and can be used in a vaccine. When this vaccine is administered to a human, the virus in it will be unable to replicate enough to cause illness, but will still provoke an immune response that can protect against future infection.

6. Merck knew and understood that continued passaging of the attenuated virus from which its Mumps Vaccine was created over 40 years ago had altered the virus and degraded its efficacy.

7. For a variety of reasons, including Merck's development and quest for approval of a new combination vaccine that contained its Mumps Vaccine, Merck initiated new efficacy testing of its Mumps Vaccine in the late 1990's. As demonstrated below, the goal of this new efficacy testing was to support its original efficacy findings at all costs, including the use of scientifically flawed methodology and falsified test results.

8. First, Merck designed a testing methodology that evaluated its vaccine against a less virulent strain of the mumps virus. After the results failed to yield Merck's desired efficacy, Merck abandoned the methodology and concealed the study's findings.

9. Second, Merck then designed another even more scientifically flawed methodology, this time incorporating the use of animal antibodies to artificially inflate the results, but this methodology also failed to achieve Merck's desired efficacy rate. Confronted with two failed methodologies, Merck then falsified the test data to obtain the results it desired. Having reached the desired--albeit falsified--efficacy threshold, Merck submitted these fraudulent results to the U.S. Food & Drug Administration ("FDA") and European Medicines Agency ("EMA").

10. Merck took steps to cover up evidence of its fraudulent testing by destroying evidence of the falsified data and then lying to an FDA investigator who questioned Merck about its ongoing testing. Merck also attempted to buy the silence and cooperation of its staff by offering them financial incentives to follow the direction of the Merck personnel overseeing fraudulent testing process. Merck also threatened a relator in the *Qui Tam* Action, Stephen Krahling, a virologist in Merck's vaccine division from 1999 to 2001, with jail if he reported the fraud to the FDA.

11. Merck continued to conceal what it knew (or should have known) about the diminished efficacy of its Mumps Vaccine, even after the United States experienced the largest mumps outbreaks in two decades in 2006 and 2009. Merck has known for over a decade that its Mumps Vaccine is far less effective than it claims. As Merck profited from its unlawful to defraud, health care providers around the country have purchased millions of doses of Mumps Vaccine with questionable efficacy, at artificially inflated prices.

PARTIES

12. Plaintiffs are residents of the State of California and pediatricians who practice in the County of Los Angeles. During the Class Period, as defined herein, Dr. Nakashima and Dr. Trompeta purchased the Mumps Vaccine from Merck at artificially inflated prices.

13. Defendant Merck is a New Jersey corporation with its vaccine division based in West Point, Pennsylvania. Merck—either directly or through its subsidiaries, which it wholly owned or otherwise controlled—manufactured, marketed, and sold Mumps Vaccine that was purchased throughout the United States, including in this District, during the Class Period. Merck is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. Merck is also a leading seller of childhood vaccines and currently markets in the United States vaccines for 12 of the 17 diseases for which the Centers for Disease Control and Prevention ("CDC") currently recommends vaccination.

14. Merck is the sole manufacturer licensed by the FDA to sell Mumps Vaccine in the United States Merck's Mumps Vaccine, together with Merck's vaccines against measles and rubella, are sold as M-M-R®II. Merck annually sells more than 7.6 million doses of M-M-R®II in the United States for which it derives hundreds of millions of dollars of revenue. Merck also has a license in the United States to sell ProQuad®, a combination vaccine containing M-M-R®II vaccine and chickenpox vaccine. Under a license from the EMA, Merck also sells Mumps Vaccine in Europe as a part of M-M-RVaxpro® and ProQuad® through Sanofi Pasteur MSD, a joint venture with the vaccine division of the Sanofi Aventis Group. Since its approval in 2005, and until 2010, ProQuade has been sold intermittently in the United States and Europe.

JURISDICTION AND VENUE

15. The federal law claims allege in Count One of this Complaint arise under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. Plaintiffs seek treble damages pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15(a). In Count Two, Plaintiffs assert claims under California law and seek to obtain restitution and secure other relief against Merck for violations of California law. Plaintiffs and the members of the Class and the California Subclass (as defined

below) also seek attorneys' fees, costs, and other litigation expenses permitted under federal and/or state law.

16. This Court has subject matter jurisdiction pursuant to Sections 4 and 12 of the Clayton Act and pursuant to 28 U.S.C. §§ 1331 and 1337.

17. This Court also has subject matter jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(d), because this is a class action in which the matter or controversy exceeds the sum of $5,000,000, exclusive of interests and costs, and in which members of the California Subclass are citizens of a state different from Defendant.

18. This Court also has supplemental jurisdiction over of the state law claims asserted herein pursuant to 28 U.S.C. § 1367 because they are so related to the federal claims asserted in this action over which this Court has original jurisdiction that they form part of the same case or controversy.

19. Venue is proper in this District pursuant to Sections 4 and 12 of the Clayton Act and 28 U.S.C. § 1391(b) and (c) because Merck can be found in and transacts business within this District, and a substantial part of the events or occurrences giving rise to the claims alleged occurred in this District. Indeed, Merck's fraudulent scheme to maintain and further its monopoly power was originated and continues to be carried out in this District at Merck's vaccine division facility located in West Point, Pennsylvania.

INTERSTATE COMMERCE

20. Throughout the Class Period, Merck manufactured, produced, sold and/or shipped substantial quantities of Mumps Vaccine in a continuous and uninterrupted flow of transactions in interstate commerce throughout the United States, including within this District. Merck's unlawful activities that are the subject of this Complaint were within the flow of, and have had a direct and substantial effect on, interstate trade and commerce.

FACTUAL BACKGROUND

A. The Market for Mumps Vaccine Has And Continues To Be Dominated By A Single Manufacturer - Merck

1. Background On The Mumps Vaccine

21. Mumps is a contagious viral disease characterized by fever, headache, muscle weakness, loss of appetite, and swelling of one or more of the salivary glands. Although severe complications are rare, the mumps virus can cause inflammation of the brain and spinal cord (among other organs), sterility, and deafness.

22. Merck first obtained approval for the Mumps Vaccine in 1967 from the Department of Biologics Standards of the National Institute of Health ("DBS"), the government agency that was at the time responsible for licensing vaccines. The vaccine was developed by Dr. Maurice Hilleman at Merck's West Point research facility, from the mumps virus that infected his five year-old daughter, Jeryl Lynn. Merck continues to use this "Jeryl Lynn" strain of the virus for its vaccine today.

23. Merck's original Mumps Vaccine was delivered to patients in a single, stand-alone injection called Mumpsvax®. In 1971, Merck developed the M-M-R® combination vaccine (incorporating vaccines for measles and rubella with the Mumps Vaccine into a single injectable) and that same year obtained DBS approval to manufacture and sell the M-M-R® vaccine in the United States. In 1978, Merck obtained approval from the FDA (which succeeded the DBS as the agency responsible for licensing vaccines) for the manufacture and sale of M-M-R®II, a replacement for M-M-R® containing a different strain of the rubella virus. Since 1978, Merck has sold more than 450 million doses of M-M-R®II world-wide, with approximately 200 million of those doses sold in the United States.

24. In September 2005, Merck obtained FDA approval for ProQuad®, a multi-disease vaccine that includes vaccinations for mumps, measles, rubella, and chicken pox in a single injection. Merck sold ProQuad in the United States from the time of its approval in 2005 until June 2007. According to Merck, the vaccine became unavailable because of certain manufacturing constraints. The vaccine was briefly available again in 2010 but has not been available since then.

2. The United States Market For Mumps Vaccine And Merck's Monopoly Power

25. As the only company licensed by the United States Government to sell Mumps Vaccine, Merck has had a monopoly and continues to have a monopoly in the United States market for Mumps Vaccine since it obtained its original license in 1967. This monopoly has extended to multi-disease vaccines such as M-M-R®, M-M-R®II, and ProQuad®. Merck has maintained this monopoly not through its legitimate business acumen and innovation or its manufacture and sale of the safest, most effective, and most cost-effective Mumps Vaccine in the market. Instead, Merck has willfully and illegally maintained its monopoly through its ongoing manipulation of the efficacy of its Mumps Vaccine. Through this unlawful conduct, Merck has been able to monopolize the Relevant Market (defined below) by both representing to the public and U.S. Government agencies a falsely inflated efficacy rate for its Mumps Vaccine and concealing what it knew about its Mumps Vaccine's diminished efficacy, all to the detriment and exclusion of potential competitors in the Market.

(a) The Relevant Geographic Market Is The United States

26. The United States (including all territories and commonwealths) is the relevant geographic market in this case. Merck manufactures and distributes its Mumps Vaccine throughout the United States. The unlawful and anticompetitive conduct at issue in this case

affects only United States sales of the relevant products. Mumps Vaccine requires FDA licensing before it can be sold in the United States.

(b) The Relevant Product Market Is The Market For Mumps Vaccine

27. The United States sale of Mumps Vaccine including, without limitation, M-M-Rell and ProQuad® (the "Relevant Market") is the relevant product market in this case.

(c) Barriers To Entry Are High In The Mumps Vaccine Market

28. There are significant barriers to entry inherent in the manufacture and sale of a new vaccine. Vaccine production is a capital-intensive, fixed-costs-based business, with the average cost to bring a vaccine to market of approximately $700 million. Moreover, the research, development, testing, and government approval process is very expensive, time-consuming, and risky. Several years and millions of dollars might be spent on developing a new vaccine only to find it fail in the final stages of testing, or to have the government refuse to approve it or significantly limit its application or distribution. Therefore, vaccine manufacturers will invest in developing a new vaccine only where they see both a need for the vaccine as an improvement over an existing vaccine and an opportunity to make a large enough return on the significant capital investment and risk involved.

29. In the case of the United States Market for Mumps Vaccine, this substantial and inherent barrier to entry is compounded by the falsely inflated efficacy rate of Merck's vaccine. As with the market for any product, a potential competitor's decision to enter a market hinges on whether its product can compete with those products already being sold in the market. If an existing vaccine is represented as being safe and at least 95 percent effective--as Merck has falsely represented its vaccine to be--it would be economically irrational for a potential competitor to bring a new Mumps Vaccine to the Relevant Market unless it thought it could

compete with the safety and efficacy of the existing vaccine. Health care providers, including Plaintiffs and the members of the Class, would not purchase it otherwise.

(d) There Is High Inelasticity Of Demand In The Mumps Vaccine Market

30. For those seeking immunization for mumps, Mumps Vaccine is the only product available to achieve that result. Regardless of the price Merck charges for its Mumps Vaccine, the extent or frequency of any price increases for the vaccine, or whether Merck incorporates the vaccine into multi-disease vaccines, as it does with M-M-RODII and ProQuad®, there are no alternative products to which the government, health care professionals, or consumers can turn to obtain this immunization.

31. The United States Market for Mumps Vaccine is further defined by the CDC's nationwide schedule of recommended childhood vaccinations, including a vaccination against mumps, and the requirement around the country that all public school students be vaccinated against mumps, among other childhood diseases. If a child is to attend public school — not to mention any private school, university, summer camp, or other educational or recreational institution in this country — he or she must be vaccinated for mumps. There is no choice (but for rare exceptions). There is no alternative. No other products can be substituted for this required vaccination.

B. Merck Willfully Maintained And Unlawfully Enhanced Its Monopoly Power In The Mumps Vaccine Market Through A Decade-Long Scheme To Defraud

32. To obtain its original government approval to sell its Mumps Vaccine, Merck conducted field studies of vaccinated children and concluded that the vaccine had an efficacy

rate of 95 percent or higher.[1] This meant that 95 percent of those given the vaccine were considered immunized against mumps. This is important because when an adequate number of people have immunity, the chances of an outbreak are reduced, and ultimately eliminated, even for people who are not vaccinated or are improperly vaccinated. This is what is known as "herd immunity." If there is insufficient immunity, a real risk of continued disease outbreaks exists. When a mumps outbreak occurs in vaccinated populations, it typically afflicts adults and older children who are at greater risk of serious complications.

33. While Merck obtained its original license in 1967, stating that its vaccine was at least 95 percent effective, Merck had known and knows that the vaccine's efficacy is significantly less than that now. Merck knows that the continued passaging of the attenuated virus to make more vaccine for distribution has altered the virus and has degraded the efficacy of the product.

34. Rather than develop a new Mumps Vaccine with greater efficacy, or prompt the development of competing vaccines by disclosing the true efficacy of its product, Merck has instead taken pains to unlawfully and unethically preserve its exclusive United States license by maintaining that its more than 40-year-old vaccine continues to have an efficacy rate of 95 percent or higher. This was easy to do for a while because Merck was able to rely on the efficacy testing it conducted in connection with the government's original granting of Merck's license to sell Mumps Vaccine. However, beginning in the late 1990's, Merck's application to change the M-M-R®II labeling in the United States and an application for a license to sell M-M-R®II in

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[1] *See* Maurice R. Hillman *et al.*, Live, Attenuated Mumps Virus Vaccine 4. Protective Efficacy as Measured in a Field Evaluation, 276 N.ENGL. J. MED. 252, 255-57 (Feb. 2, 1967).

Europe required new efficacy testing of its Mumps Vaccine. This testing also coincided with Merck's development and quest for approval of ProQuad® in both the United States and Europe.

35. If Merck failed to demonstrate that its Mumps Vaccine was still 95 percent effective, it risked losing the monopoly it had over the sale of Mumps Vaccine in the United States. With respect to M-M-R®II or Mumpsvax®, additional competition would have driven down the price of the vaccines. Plaintiffs, the members of the Class, and the members of the California Subclass would either have obtained a better price for the vaccine or stopped purchasing the vaccine from Merck altogether. With respect to ProQuad®, the government might not have approved the vaccine at all for sale in the United States. Under any of these scenarios, Merck risked losing hundreds of millions of dollars in revenue from this very profitable but unlawful monopoly.

36. Because of this, Merck set out to conduct testing of its Mumps Vaccine that would support its original efficacy finding. In performing this testing, Merck was determined to report a seroconversion rate of 95 percent or higher, regardless of the vaccine's true efficacy. As it turned out, the only way Merck could accomplish these results was through manipulating its testing procedures and falsifying the test results. Relators to the *Qui Tam* Action participated on the Merck team that conducted this testing and witnessed first-hand the scheme to defraud to which Merck resorted to obtain its desired results. Merck internally referred to the testing as Protocol 007.

1. Merck Manipulated And Falsified Test Results To Distort The True Efficacy Of Its Mumps Vaccine

(a) Merck's Abandonment Of Its Original PRN Test And Test Results

37. The original methodology Merck employed under Protocol 007 was a Mumps Plaque Reduction Neutralization ("PRN") Assay. Preliminary testing commenced in 1999 at

Merck's West Point facility and was led by Senior Investigator David Krah ("Krah") and his second-in-command, Mary Yagodich ("Yagodich"). Merck's Executive Director of Vaccine Research, Alan Shaw ("Shaw"), approved the testing methodology that Krah and Yagodich employed. Relator Krahling witnessed Krah and Yagodich as they conducted the preliminary testing.

38. As the name of the test indicates, the PRN test measures the virus neutralization that occurs after administration of the Mumps Vaccine. Merck's first test was in some measure similar to the testing procedure regarded in the scientific community as the "gold standard" for testing how well a vaccine works. Blood samples are taken from children both before they receive the vaccine and again after they have been injected with the vaccine after sufficient time has passed for the vaccine to produce an immune response. The paired blood samples are then individually incubated with the target virus and added to sheets of cells. Where the virus replicates in the cell sheet it leaves a plaque or hole.

39. The pre-vaccinated child will not typically have immunity to the disease. Therefore, the pre-vaccinated blood will be unable to neutralize the virus and plaques will form where the virus has infected the cells. In contrast, if the vaccine has stimulated the child's immune system to develop antibodies against the virus, the post-vaccinated blood will neutralize the virus. The post-vaccinated blood sample will consequently show a smaller number of plaques, or holes, in the cell sheet compared to the pre-vaccinated sample.

40. A PRN test simply compares virus growth in the presence of the pre- and post-vaccinated blood samples. The number of plaques (where the virus has grown) is compared to determine if the vaccine caused the child to develop a sufficient level of antibodies to neutralize the virus. Results are reported in terms of seroconversion. A seroconversion occurs when the pre-

vaccination blood sample is "negative" (meaning insufficient antibodies to neutralize the virus) and the post-vaccination sample is "positive" (meaning sufficient antibodies to neutralize the virus). Seroconversion occurs, therefore, when a blood sample goes from "pre-negative" (insufficient antibodies) to "post-positive" (sufficient antibodies). In the laboratory, seroconversion is the best correlate for efficacy — how successful the vaccine is at immunizing children. For the purposes of its testing, Merck was looking for a seroconversion rate of 95 percent or higher to support its original efficacy finding and the efficacy it continued to represent in its labeling.

41. While Merck's PRN test was modeled after the neutralizing test generally accepted in the industry, it diverged from this "gold standard" test in a significant way. It did not test the vaccine for its ability to protect against a wild-type mumps virus. A wild-type virus is a disease-causing virus. That is the type of real-life virus against which vaccines are generally tested. Instead, Merck tested the children's blood for its capacity to neutralize the attenuated Jeryl Lynn strain of the virus. This was the same mumps strain with which the children were vaccinated. The use of the attenuated Jeryl Lynn strain, as opposed to a virulent wild-type strain, subverted the fundamental purpose of the PRN test, which was to measure the vaccine's ability to provide protection against a disease-causing mumps virus that a child would actually face in real life. The end result of this deviation from the accepted PRN gold standard test was that Merck's test overstated the vaccine's effectiveness.

42. Even with a deviation that could only overstate how well the vaccine worked, the results from Merck's preliminary testing, which involved testing blood samples of approximately 60-100 children, yielded seroconversion rates significantly below the desired 95 percent threshold. Krah admitted as much to Relator Krahling. Krah also admitted to Relator Krahling

that the efficacy of Merck's vaccine had declined over time, explaining that the constant passaging of virus to make more vaccine for distribution had degraded the product and that because of this, mumps outbreaks would increase over time.

43. Krah further admitted to Relator Krahling that he and Yagodich tried numerous other, often undocumented, techniques to modify the PRN test to improve the seroconversion results they could measure, including trying different virus dilutions, different staining procedures and even counting plaques more liberally. These other techniques — like using the vaccine strain rather than a wild-type strain of the virus — subverted the purpose of the PRN test. In the end, however, none of it mattered. Merck had to abandon its methodology because no matter how Krah and Yagodich manipulated the procedures, they could not reach the 95 percent seroconversion threshold.

44. To reach this threshold, Merck abandoned the PRN methodology that yielded unsatisfactory results and worked towards developing a new, rigged methodology that would allow Merck to report its desired seroconversion results.

(b) Back To The Drawing Board: Merck's Improper Use Of Animal Antibodies In Its "Enhanced" PRN Test

45. The new methodology Merck devised and ultimately used to perform the mumps efficacy testing under Protocol 007 was an "enhanced" PRN Assay. It was again led by Krah and approved by Shaw and commenced in 2000. Relators Krahling and Wloehowski participated on the team that conducted the testing using this supposedly enhanced methodology. Each of them witnessed first-hand the falsification of the test data in which Merck engaged to reach its 95 percent seroconversion threshold. In fact, each of them was significantly pressured by Krah and other senior Merck personnel to participate in this scheme to defraud.

46. From the outset, Merck's objective with this "enhanced" procedure was clear. It was not to measure the actual seroconversion rate of Merck's Mumps Vaccine; rather, it was to come up with a methodology that would yield a minimum 95 percent seroconversion rate regardless of the vaccine's true efficacy. The very first page of an October 2000 Merck presentation on the "enhanced" methodology stated just that:

> Objective: Identify a mumps neutralization assay format. .. that permits measurement of a ≥ 95% seroconversion rate in M-M-R®II vaccines.

Nowhere in this presentation did Merck provide any kind of justification or explanation for abandoning its original PRN methodology and the unsatisfactory seroconversion results it yielded.

47. To reach the stated objective for its "enhanced" test and increase the measured seroconversion rate to the predetermined 95 percent threshold, Merck continued to use its scientifically flawed PRN methodology — that tested against the vaccine strain rather than a wild-type strain — but with one additional material change. Merck added animal antibodies to both the pre- and post-vaccination blood samples. The use of animal antibodies in laboratory testing is not uncommon. They can serve as a highlighter of sorts to identify and count human antibodies that otherwise might not be identifiable on their own. When used in that way, animal antibodies make it easier to see the human antibodies. They do not alter what is being measured. However, Merck added animal antibodies for the singular purpose of altering the outcome of the test by boosting the amount of virus neutralization counted in the laboratory.

48. In a laboratory setting, animal antibodies can combine with human antibodies to cause virus neutralization that would not otherwise occur from the human antibodies alone. Merck's "enhanced" methodology permitted various types of human antibodies to be counted as mumps neutralizing antibodies when it was actually the animal antibodies combining with those

human antibodies causing the neutralization. Merck also did not apply a proper "control" to isolate whether virus neutralization was caused by the human antibodies alone or in combination with the animal antibodies. Rather, Merck included in its seroconversion measure all virus neutralizations, regardless of whether they resulted from human antibodies or by their combination with the animal antibodies. This "enhanced" PRN methodology thereby allowed Merck to increase dramatically the recordable instances of mumps virus neutralization and to count those neutralizations toward seroconversion and its measure of the vaccine's success.

49. Merck knew that the neutralizations attributable to the animal antibodies would never exist in the real world. This is because the human immune system, even with the immunity boost provided by an effective vaccine, could never produce animal antibodies. Adding this external factor as a supplement to a vaccine was not an option because it could result in serious complications to a human or even death. Thus, the "uncontrolled" boost to neutralization Merck designed using these animal antibodies in its laboratory did not in any way correspond to, correlate with, or represent real-life (in vivo) virus neutralization in vaccinated people.

50. However, the use of the animal antibodies allowed Merck to achieve its high seroconversion objectives. In fact, paired blood samples that were found under Merck's 1999 PRN methodology to lack sufficient virus neutralizing antibodies were now considered seroconverted using the "enhanced" methodology. Indeed, in one panel of 60 paired blood samples, Merck measured a seroconversion rate of 100 percent. In other words, non-neutralizing concentrations of antibodies that would never protect a child from mumps in the real world were, under Merck's "enhanced" methodology, treated as vaccine successful solely because of the additional neutralization provided by the animal antibodies.

51. Krah defended the use of the animal antibodies in the "enhanced" PRN test by pointing to the FDA's purported approval of the process. However, whatever FDA approval Merck may have received for this testing, there is no indication that the FDA was fully aware of the extent of Merck's manipulation of the testing, including Merck's wholesale fabrication of test data to reach its preordained 95 percent efficacy threshold.

(c) Back To The Drawing Board Again: Merck's Falsification Of The "Enhanced" PRN Test Results

52. There was a significant problem with Merck's improper use of the animal antibodies to boost its virus neutralization counts that would be evident to any competent scientist reviewing the test data. The animal antibodies boosted neutralization counts not only in the post-vaccination blood samples, but also in the pre-vaccination samples. However, too much virus neutralization in the pre-vaccinated sample created a "pre-positive," which means enough virus neutralization to characterize the child as immune without the vaccine.

53. Pre-positives ordinarily occur in a small percentage of the child population that is immune to mumps even without vaccination. This immunity would principally come from a previous exposure to the mumps virus, or from immunity transferred to a child from the mother in utero. However, the incidence of this immunity is small, generally measured by the scientific community at around 10 percent of the child population.

54. The problem for Merck was that, with the addition of the animal antibodies to the pre-vaccination blood samples, it was seeing a significantly higher percentage of pre-positives than the ten (10) percent industry recognized occurrence of such immunity. In the results of one test that Relators Krahling and Wlochowski both witnessed in Summer 2001, the pre-positive rate was more than 80 percent. Krah instructed Wlochowski to throw out the results and the

actual experimental plates of that particular test, thereby destroying all traces of the unwanted results.

55. The existence of such a high percentage of pre-positives threatened the viability of Merck's "enhanced" methodology. As a practical matter, with a pre-positive, any favorable results in the post-vaccinated sample could not be counted as a vaccine success toward the 95percent seroconversion target. A sample appearing positive before the vaccine, and staying positive after the vaccine, was not a seroconversion.

56. Just as important, the high pre-positive rate would red flag the methodology as flawed. The FDA would invariably question the results of a test that had such a high level of pre-positives. Krah stated this explicitly to the members of his laboratory, including Relators Krahling and Wlochowski. If Merck wanted to keep the artificial boost in post-vaccination positives provided by the animal antibodies, it would have to eliminate the associated boost in pre-vaccination positives.

57. In the October 2000 presentation, Merck acknowledged that its initial "enhanced" PRN testing results yielded a level of pre-positives that was too high. Merck also made clear that it needed to "optimize" the amount of animal antibodies used in the process so that the testing would yield a pre-positive rate of 10 percent or less and a seroconversion rate of 95 percent or more: "Pre-positive rate is higher than desirable," and "Continue evaluation of results using optimized [animal antibodies] amount (target $\leq$ 10% pre-positive rate and $\geq$ 95% seroconversions)."

58. The problem was that no matter how it was manipulated, no amount of animal antibodies added would produce a pre- and post-vaccination virus neutralization for Merck's vaccine within the desired range. Without the animal antibodies, Merck could not support a

sufficient level of post-vaccination neutralization. Conversely, by adding the animal antibodies, Merck could not avoid having too high a level of pre-vaccination neutralization (*i.e.*, too many pre-positives). This left only one way for Merck to reach its desired seroconversion outcome - namely, to falsify the test results.

59. Specifically, Krah and Yagodich and other members of Krah's staff falsified the test results to ensure a pre-positive neutralization rate of below ten (10) percent. They did this by fabricating their plaque counts on the pre-vaccination blood samples, essentially counting plaques that were not actually there. With these inflated plaque counts, Merck was able to count as pre-negative those blood samples that otherwise would have been counted as pre-positive because of the increased neutralization caused by the animal antibodies.

60. Merck's falsification of the pre-vaccination plaque counts was performed in a broad-based and systematic manner from December 2000 until at least August 2001:

- Krah stressed to his staff that the high number of pre-positives they were finding was a problem that needed to be fixed.
- Krah directed his staff to re-check any sample found to be pre-positive to see if more plaques could be found to convert the sample to a pre-negative.
- Krah and Yagodich falsified plaque counts to convert pre-positives to pre-negatives, and directed other staff scientists to do the same.
- Krah appointed Yagodich and two others to "audit" the testing that other staff scientists had performed. These audits were limited to finding additional plaques on pre-positive samples thereby rendering them pre-negatives.
- Krah instituted several measures to isolate the pre-positive samples, to facilitate their "re-count," and to convert them to pre-negatives. For example, when manually changing original counting sheets proved too time-consuming, Krah employed an Excel spreadsheet which would automatically highlight the undesirable pre-positives so that they could be targeted more efficiently. The data was entered, highlighted, and changed before it was ever saved.
- Krah also engaged in the destruction of evidence to minimize the chances of detection. He not only used an Excel spreadsheet to avoid a paper trail, he also

destroyed test results, substituted original counting sheets with "clean" sheets, and ordered the staff in the laboratory to do the same.

- In March 2001, Merck cancelled a planned outsource of the testing to a laboratory in Ohio because the outside laboratory was unable to replicate the seroconversion results Krah was obtaining in his laboratory. Krah and his staff conducted all the remaining testing instead.

61. Unsurprisingly, none of the "recounting" and "retesting" that Krah and his staff performed as part of the "enhanced" testing was performed on any post-vaccination samples or on any pre-vaccination samples that were pre-negative. This additional "rigor" was only applied to the pre-positive samples, the very samples Merck had identified as undesirable and which kept Merck from attaining its target of < 10% pre-positive rate and > 95% seroconversion.

62. Relators Krahling and Wlochowski engaged in numerous efforts to stop the scheme to defraud. They questioned and complained to Krah about the methodology being employed, particularly the manipulation of pre-positive data. They attempted to dissuade others from participating. They initiated numerous telephone calls to the FDA to expose the scheme to defraud. They attempted to document the scheme to defraud, even as evidence of it was being destroyed. But Relators' valiant efforts were to no avail. For every effort they took to stop the scheme to defraud, Merck adapted the scheme to assure the falsification continued. For example, when Relators objected to changing their own plaque counts, Krah appointed other staff, as so-called auditors, who were willing to falsify the data.

63. In July 2001, Relators Krahling and Wlochowski secretly conducted their own audit of the test results to confirm statistically the fraud that was occurring with the "enhanced" testing. They reviewed approximately 20 percent of the data that Merck had collected as part of the "enhanced" test. In this sampling, they found that 45 percent of the pre-positive data had been altered to make it pre-negative. No pre-negatives were changed to pre-positives. No post-positives were changed to post-negatives. No post-negatives were changed to post-positives. The

statistical probability of so many changes occurring in just the pre-positive data and in no other data was more than one trillion to one. Indeed, that is a conservative measure given the likelihood that an even greater number of pre-positives were changed but remained undetected because the changes were not recorded in Merck's files.

(d) The Complicity Of Merck's Senior Management

64. Krah did not act alone in orchestrating the falsification of the "enhanced" PRN test results. He acted with the knowledge, authority, and approval of Merck's senior management.

65. For example, in April 2001, after Merck cancelled the planned outsourcing of the remainder of the Mumps Vaccine efficacy testing, Emilio Emini ("Emini"), the Vice President of Merck's Vaccine Research Division, held a meeting with Krah and his staff, including Relators Krahling and Wlochowski. Emini was clearly on notice of protests occurring in the laboratory because he directed Krah's staff to follow Krah's orders to ensure the "enhanced" testing would be successful. Emini also told the staff that they had earned very large bonuses for the work they had completed on the project so far. He told them he was going to double the bonuses and pay them once the testing was complete.

66. In July 2001, after completing the secret audit, Relator Wlochowski openly accused Krah during a laboratory meeting of committing fraud in the Mumps Vaccine testing. Relator Krahling then met with Shaw and confronted him about the fraudulent testing. Krahling told Shaw of the falsification of the pre-positive data. Krahling also confronted Shaw about the improper use of the animal antibodies to inflate the post-vaccine neutralization counts. Shaw responded that the FDA permitted the use of the animal antibodies and that should be good enough for Krahling. Shaw refused to discuss anything further about the matter. Instead, Shaw

talked about the significant bonuses that Emini had promised to pay the staff in Krah's laboratory once the testing was complete.

67. Relator Krahling then met with Bob Suter ("Suter"), Krahling's human resources representative at Merck. Krahling told Suter about the falsification of data and Shaw's refusal to get involved. Krahling told Suter that he was going to report the activity to the FDA. Suter told him he would go to jail if he contacted the FDA and offered to set up a private meeting with Emini where Krahling could discuss his concerns.

68. Shortly thereafter, Emini agreed to meet with Krahling. In an early August 2001 meeting with Emini, Krahling brought actual testing samples and plaque counting sheets to demonstrate to Emini the fraudulent testing that Krah was directing. Emini agreed that Krah had falsified the data. During the meeting, Krahling also protested against the use of the animal antibodies to inflate the seroconversion rate. Emini responded that the animal antibodies were necessary for Merck to achieve the project's objective. Krahling proposed a scientific solution to lower the pre-positive rate and end the need to falsify data — namely, to stop using the animal antibodies. When Emini declined, Krahling asked him what scientific rationale justified using the animal antibodies. Emini stated that Merck's choice to use the antibodies was a "business decision."

69. To assuage Krahling's concerns, Emini promised to conduct an "internal audit" of the Mumps Vaccine testing. Krahling countered that the FDA should be contacted because only the FDA could perform an audit that was truly independent. Emini ordered Krahling not to call the FDA. Immediately after the meeting, Suter approached Krahling and again threatened that he would be put in jail if he contacted the FDA.

70. The next morning, Krah arrived early to the laboratory and packed up and destroyed evidence of the ongoing Mumps Vaccine testing. This evidence included garbage bags full of the completed experimental plates, containing the cell sheets with plaques, that would have (and should have) been maintained for review until the testing was complete and final. The destruction of the plates would make it difficult to compare the actual plaque counts in the test with what was documented and changed on the counting sheets, as Krahling had done the day before in Emini's office. Despite the threats he received from Suter and Emini, Krahling called the FDA again and reported this latest activity in Merck's ongoing scheme to defraud.

(e) The FDA Interview Of Krah And Shaw

71. On August 6, 2001, in response to Relator Krahling's complaint, an FDA agent came to Merck to question Krah and Shaw. The FDA agent's questions were largely focused on Merck's process for counting plaques in the "enhanced" PRN test. Krah and Shaw misrepresented the process that Merck was actually conducting and the fact that Merck was falsifying the pre-positive test data.

72. For example, the FDA agent asked whether there was any ad hoc revisiting of plaque counts. Krah falsely responded that plaque counts were being rechecked only for verification and controls and to check hypervariability. Krah also misrepresented to the FDA agent that they did not change the data after it was entered in the Excel spreadsheet. When the FDA agent pressed Krah on the criteria for changing original counts on the counting sheets, Krah left the interview without answering the question. In Krah's absence, Shaw informed the FDA agent that a memo would be added to the standard operating procedure to address changes. The FDA agent then asked Shaw why they had not taken care of this before the project started. Shaw offered that Krah and another Merck employee had identified "trends" and "problems" with the original counts without ever explaining what those "trends" or "problems" actually were.